

## REMARKS

Claims 7, 8, 10-12, 28-35, 37-40, 43, 44, 46, 47 and 54-56 are pending in the application with entry of this Amendment. Claims 9, 45 are canceled without prejudice. Claims 7, 28 and 43 are amended. The amendments do not present new matter. See, e.g., Figs. 31-32; p. 37, lines 12-13 (soft, flexible biocompatible material). Applicant notes that there is no requirement that a claim amendment must include exactly the same nomenclature as provided in the specification. MPEP §608.01. Claims 12 and 29 were withdrawn from consideration. It is respectfully requested that these claims be reinstated upon allowance of respective independent claims from which they depend.

It is stated in the Office Action that the language “the suction device being removably securable to myocardial tissue” is objected to and interpreted as intended use and/or functional language. These claims are amended to recite *inter alia* “the suction device having a shape and a size for being removably securable to myocardial tissue.” Therefore, Applicant respectfully requests that the objection and related allegations are moot.

Reconsideration and allowance of the application, as amended, are respectfully requested.

### I. Withdrawn Rejections / New Rejections

Applicant kindly acknowledges that the prior rejection of claims 7, 9-11, 28, 30, 40, 43 and 45-47 under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 4,736,749 to Lundback has been withdrawn. Claims 7-11, 28, 30, 40 and 43-47 are currently rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Lundback in view of U.S. Patent No. 6,185,442 to Samson (“Samson”).

Applicant also kindly acknowledges that the prior rejection of claims 31-33 and 37-39 under 35 U.S.C. §103(a) as allegedly being unpatentable over Lundback in view of U.S. Patent No. 4,685,466 to Rau (“Rau”) has been withdrawn. Claims 31-33 and 37-39 are now rejected as allegedly being unpatentable over Lundback in view of Samson and further in view of Rau.

Applicant also kindly acknowledges that the prior rejection of claims 34-35 under 35 U.S.C. §103(a) as allegedly being unpatentable over Lundback in view of U.S. Patent No. 7,020,531 to Colliou et al. (“Colliou”) has been withdrawn. Claims 34-35 are now rejected as allegedly being unpatentable over Lundback in view of Samson and further in view of Colliou.

## II. Claims 7, 8, 10, 11, 28, 30, 40, 43, 44, 46 and 47 Are Patentable Over Lundback and Samson

Independent claims 7, 28 and 43 and respective dependent claims 8, 10, 11, 30, 40, 44, 46 and 47 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Lundback in view of Samson. Applicant respectfully submits that the rejection is moot in view of the claims as amended.

It is conceded in the Office Action that Lundback fails to disclose “a distal surface that has normal vector (a direction transverse and away from the surface) that is aligned with the central longitudinal axis of the tube. If Applicant’s interpretation of this concession is correct, it is also conceded that Lundback fails to disclose, teach or suggest the structural configuration of a tube defining an axis and a suction device “connected to and coaxial with the distal end of the tube and having a distal surface, a width of the distal surface being greater than a width of the distal end of the tube” as recited in claims 1, 28 and 43. Clarification is respectfully requested if the Applicant’s understanding is not correct.

Lundback fails to disclose, teach or suggest “a suction device formed from a flexible material” as recited in claim 7, “a suction device formed from a flexible material” as recited in claim 28, and “a suction device formed from a flexible material” as recited in claim 43. It is alleged in the Office Action that the vacuum tube 8 (Lundback, col. 3, line 34) is the “tube” as recited in claims 1, 28 and 43, and that the collection of the arrangement 1 (Lundback col. 3, line 13), the intermediate element 2 (Lundback, col. 3, line 18) and the backpiece 3 (Lundback, col. 3, line 16).

However, Lundack explains that the backpiece 3 connected to the hose is rigid and advantageously made of plastic. Lundback (Abstract; col. 2, line 5; col. 3, lines 23-24; col. 5, lines 28-29) A “rigid” backpiece is not, by definition, flexible. Similarly, the intermediate element 2 described by Lundback has “a relatively rigid ring portion 9 with a circumferential sealing lip 13...” (Lundback, col. 3, line 46) (emphasis added). A flange 17 on the intermediate element 2 elastically abuts against a lip 16 of the rigid backpiece 3, but the intermediate element 2 is made from silicon rubber or a similar material so that the intermediate element “has a relatively rigid ring.” Moreover, the ring 9 of the intermediate element is a “relatively rigid ring.” Lundback (col. 4, line 3) (emphasis added). Accordingly, Lundback fails to disclose, teach

or suggest a suction device formed from a flexible material. Moreover, Lundback teaches away from a suction device formed from a flexible material since Lundback explains that the rigid backpiece is advantageously made of plastic.

Lundback also fails to disclose, teach or suggest “the tissue stimulation element being supported on the suction device distal surface” as recited in claims 7 and 28, and “tissue stimulation means, carried by the suction device distal surface” as recited in claim 43. It is alleged that the “suction device” as recited in the claims is the collection of the arrangement 1, the intermediate element 2, and the backpiece 3. Office Action (p. 2). Based on the Office Action allegations, the distal surface of the collection of these components would be the sealing lip 13 of the intermediate element 2. Lundback (Figs. 1-3). The operative part 30 described by Lundback is positioned above the sealing lip 13, i.e., within an intermediate space, and therefore, is not carried by a distal surface of a suction device.

Additionally, Lundback is related to a diagnostic or therapeutic arrangement for attachment to a skin surface (i.e., an outer surface of a body) as opposed to having a shape and a size for being removably securable to myocardial tissue, which is inside the body.

Lundback also fails to disclose, teach or suggest the limitation, “wherein the suction device is substantially cup-shaped” recited in claims 10 and 46. The Office Action has not explained how the collection of the arrangement 1, the intermediate element 2 and the backpiece 3 is cup-shaped.

In an attempt to fill these determinative deficiencies of Lundback, the Office Action relies on Samson as allegedly disclosing a suction device, tube and electrode, and that a distal surface of the suction device has a normal vector that is aligned with the central axis of the tube. Office Action (p. 3). Samson, however, does not disclose, teach or suggest the combination of “the suction device ... having a distal surface, a width of the distal surface being greater than a width of the distal end of the tube” and “the tissue stimulation element being supported on the suction device distal surface” as recited in claims 7 and 28 and “the suction device ... having a distal surface, a width of the distal surface being greater than a width of the distal end of the tube” and tissue stimulation means, carried by the suction device distal surface ...” as recited in claim 43.

In contrast, Samson describes an electrode 16 that is “mounted within the suction cup [10].” Samson (col. 3, line 47; Fig. 2) (emphasis added). An electrode that is within or inside a

suction cup cannot be supported on a suction device distal surface as recited in claims 7, 28 and 43, particularly considering that claims 7, 28 and 43 also recite that the width of the distal surface is greater than a width of the distal end of the tube. Thus, with the configuration recited in the claims, a tissue stimulation element is supported on a suction device distal surface that extends outwardly relative to an axis defined by the tube as a result of having a larger width or diameter, whereas Samson describes an electrode that is within or inside a suction cup and centrally disposed inside the cup. Samson explains that the reason for this particular configuration is to enable a user to manipulate a bellows 14 so that the electrode 16 may be drawn down into contact with the scalp of a fetus. Samson (col. 3, lines 44-46, 57-61; Fig. 2 (illustrating user pushing bellows with thumb and to move electrode 16).

Samson also fails to disclose, teach or suggest “a tissue stimulation element that is too small to form a transmural lesion in myocardial tissue” as recited in claims 7, 28 and 43. In stark contrast, Samson describes a probe having a suction cup 10 “intended for attachment to the head 11 of a fetus for the purpose of monitoring characteristics of the fetus.” Moreover, based on the Figures in Samson, the configuration recited in claims 7, 28 and 43 is not possible since diameter of the electrode 16 shown by Samson is significantly larger than the width of the rim 13, and therefore, the rim 13 is not suitable for supporting the large electrode. Further, such modifications would substantially alter the configuration and use of the device described by Samson and/or render the device described by Samson inoperable for its intended purpose.

Consequently, Samson does not cure all of the deficiencies of Lundback and has its own deficiencies. Lundback and Samson, individually and on combination, fail to disclose, teach or suggest each limitation of each rejected claim, which is the first requirement of any rejection under 35 U.S.C. §103(a). Further, Samson teaches away from Applicant's claims given the reasons for an electrode 16 being within a suction cup as opposed to on a distal surface having a width greater than a tube, and permitting a user to move the electrode within the suction cup by contraction of the bellows 14.

Applicant respectfully requests that the rejection of independent claims 7, 28 and 43 are patentable over Lundback and Samson. Dependent claims 8, 10, 11, 30, 40, 44, 46 and 47 incorporate the elements and limitations of respective independent claims 7, 28 and 43 and, therefore, are also believed allowable. MPEP §2143.03. Accordingly, applicant respectfully requests that the rejection of these claims under §103(a) be withdrawn.

### **III. Claims 31-33 and 37-39 Are Patentable Over Lundback, Samson and Rau**

Dependent claims 31-33 and 37-39 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Lundback in view Samson and further in view of U.S. Patent No. 4,685,466 to Rau ("Rau"). Dependent claims 31-33 and 37-39 incorporate the elements and limitations of respective independent claims 7, 28 and 43 and, therefore, are also believed allowable. MPEP §2143.03.

It is conceded in the Office Action that Lundback and Samson fail to disclose certain stimulation electrode dimensions as recited in the claims. Rau is cited for this limited purpose. Rau, however, does not disclose, teach or suggest all of the above-discussed claim limitations missing in Lundback and Samson.

The Office Action cites col. 3, lines 1-15, col. 4, lines 29-49 and Figures 4-6 of Rau to support the rejection. It is stated in the Office Action that "Rau provides all of the recited dimensions" of the claimed invention based on Rau disclosing a needle. Office Action. (p. 4). However, the cited sections of Rau do not recite any specific dimensions for the needle, and there is no evidence set forth in the Office Action to establish that the needle described by Rau necessarily has the dimensions as recited in claims 31-33 and 37-39.

Moreover, a person of ordinary skill in the art would not combine the cited references. It is alleged in the Office Action that it would have been obvious to combine Lundback and Rau and modify Lundback to provide a suction electrode with a needle electrode in order to provide fixation without electrode paste or jelly to reduce skin resistance. Office Action (p. 5). However, Lundback does not even refer to "paste" or "jelly." The alleged reason for combining Lundback and Rau is described in Rau itself, not Lundback. Accordingly, the basis for the reason for combining the references is not clear. If the rejection stands, Applicant respectfully requests the Examiner to identify the section of Lundback that describes use of paste or jelly and the reason for use of a needle electrode in Lundback.

Applicant also respectfully submits that a person of ordinary skill in the art would not combine the cited references given the particular and different structural configurations and functionality. It is alleged in the Office Action that the electrode provides a needle configuration "to provide fixation." Office Action (p. 4). More specifically, Rau explains that the needle point penetrates into cell layers of the skin to provide "an exceptionally effective fastening of the

electrode” to the skin. Rau (col. 3, lines 46-49). However, Lundback explains “the holder is held firmly by suction” against the skin when the vacuum valve is re-opened. Lundback (Abstract) (emphasis added), and Samson explains that vacuum is used to cause a suction cup 10 to deform and be “secured to the fetal head.” Samson (col. 3, lines 59-61. Thus, a needle point as described by Rau is not required in the devices described by Lundback and Samson since devices are already held firmly against or secured to skin.

Further, Rau explains that use of the needle point to penetrate cell layers of the skin results in “indention points” that are formed in the skin. Samson, however, describes securing a suction cup having an electrode by vacuum to a head of a fetus in a “non-invasive” manner using vacuum and a suction cup. Samson (Abstract). Applicant respectfully submits that a person of ordinary skill in the art would not combine Samson and Rau since it would not be desirable to use a needle point to penetrate the skin of a fetal head and form indention points (even if temporary) in a fetal head when Samson achieves its objectives in a non-invasive manner by use of suction.

Further, it is alleged that such modifications for purposes that are not described by Lundback would be used “to reduce skin resistance.” In this regard, Rau is referring to electrical resistance of the skin to obtain more accurate measurement results with reduced interfering signals (movement artifacts, noise, etc.). Lundback, however, does not even discuss electrical resistance of the skin.

Accordingly, Applicant respectfully submits that the rejection of dependent claims 31-33 and 37-39 are patentable over Lundback, Samson and Rau, and respectfully request that the rejection of these claims under §103(a) be withdrawn.

**IV. Claims 34 and 35 Are Patentable Over Lundback, Samson and Colliou**

Dependent claims 34 and 35 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Lundback in view of Samson and further in view of U.S. Patent No. 7,020,531 to Colliou ("Colliou"). Dependent claims 34 and 35 incorporate the elements and limitations of independent claim 28 and, therefore, are also believed allowable.

It is conceded that Lundback fails to disclose that the source of stimulation is configured to provide stimulation pulses that are about 1 msec in duration, 10mA and two stimulation pulses per second, and cites Colliou for this limited purpose. Colliou, however, does not provide the above-discussed claim limitations missing in Lundback and Samson. Therefore, the cited references, individually and in combination, fail to disclose, teach or suggest each element of claims 28, 34 and 35.

Further, Applicant respectfully submits that a person of ordinary skill in the art would not combine the cited references since they describe devices having different structural configurations for different purposes. Lundback is directed to a suction / vacuum device for attachment to skin (Lundback, col. 2, line 1), Samson is directed to a suction device that is secured to a fetal head (Samson, col. 3, line 37), and Colliou is directed to a device that is attached to a stomach wall (Colliou, Abstract).

Accordingly, dependent claims 34 and 35, which incorporate the elements and limitations of independent claim 28, are believed allowable over the cited references.

**CONCLUSION**

Applicant respectfully requests entry of this Amendment and allowance of the application in view of the forgoing remarks. If there are any remaining issues that can be resolved by telephone, Applicant invite the Examiner to kindly contact the undersigned at the number indicated below.

Respectfully submitted,

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